



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request; NIH Electronic Application System for NIH Certificates of Confidentiality

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the Office of Extramural Research (OER), in the Office of the Director, the National Institutes of Health (NIH) will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Pamela Reed Kearney, Division of Human Subjects Research, OER, NIH, 6705 Rockledge Dr., Building Rockledge 1, Room 812–C, Bethesda, MD 20817, or call non-toll-free number (301) 402-2512 or E-mail your request, including your address to: NIH-CoC-Coordinator@mail.nih.gov.

Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical

utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Electronic Application for NIH Certificates of Confidentiality (CoC E-application System), 0925-0689, REVISION, exp., date 02/28/2023. Office of Extramural Research (OER), National Institutes of Health (NIH).

Need and Use of Information Collection: The current CoC system sends system communications and the approved Certificate to the Principal Investigator and the Institutional Official. NIH is adding two optional data fields to the electronic system for the submission and processing of requests for NIH to issue Certificates of Confidentiality (CoCs). The optional data fields will allow the requester to identify another person that receives CoC system communications and the approved Certificate. This request system provides one electronic form to be used by all research organizations that request a Certificate of Confidentiality (CoC) from NIH. As described in the authorizing legislation (Section 301(d) of the Public Health Service Act, 42 U.S.C. 241(d)), CoCs are issued by the agencies of the U.S. Department of Health and Human Services (HHS), including NIH, to authorize researchers to protect the privacy of human research subjects by prohibiting them from releasing names and identifying characteristics of research participants to anyone not connected with the research, except in limited circumstances specified in the statute. At NIH, the issuance of CoCs has been delegated to the NIH Office of Extramural Research (OER) in the NIH Office of the Director. NIH received 795 requests for CoCs from January 2020 through December 2020 and expects to receive approximately the same number of requests in subsequent years. NIH has been using an

online CoC system to review requests and issue CoCs since 2015. The current CoC request form includes six sections of information collected from research organizations. The information provided is used to determine eligibility for a CoC and to issue the CoC to the requesting organization. Eligible requesting organizations that provide legally binding affirmations that they will abide by the terms of the CoC are issued a Certificate of Confidentiality. This system has increased efficiency and reduced burden for both requesters and NIH staff who currently process these requests.

OMB approval is requested for three years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1193.

Estimated Annualized Burden Hours

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Time Per Response (in hours)	Total Annual Burden Hour
Life Scientists	795	1	90/60	1193
TOTAL		795		1193

Dated: December 11, 2021.

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National Institutes of Health.

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